

ATTACHMENT 1

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# **Guidance for Industry**

## **Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**October 2002  
OTC**

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**GDL-2**

Example Drug Facts Label for Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form

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**Drug Facts**

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**Active ingredient (in each [insert dosage unit])**

**Purposes**

Naproxen sodium 220 mg (naproxen 200 mg).....Pain reliever/fever reducer

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**Uses**

- temporarily relieves minor aches and pains due to:
    - headache    ■ muscular aches    ■ minor pain of arthritis    ■ toothache
    - backache    ■ the common cold    ■ menstrual cramps
  - temporarily reduces fever
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**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include:

- hives    ■ facial swelling    ■ asthma (wheezing)    ■ shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers.

Naproxen sodium may cause stomach bleeding.

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**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer

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**Ask a doctor before use if you have** ever had serious side effects from any pain reliever or fever reducer

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**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
  - taking any other drug
  - taking any other product that contains naproxen sodium, or any other pain reliever/fever reducer
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**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- you develop heartburn
- stomach pain occurs or lasts, even if symptoms are mild

- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- **do not take more than directed**
- drink a full glass of water with each dose

Adults and children 12 years and older	<ul style="list-style-type: none"> <li>■ take 1 [insert dosage unit] every 8 to 12 hours while symptoms last</li> <li>■ first dose - you may take 2 [insert dosage unit(s)] within the first hour</li> <li>■ the smallest effective dose should be used</li> <li>■ do not exceed 2 [insert dosage unit(s)] in any 8- to 12-hour period</li> <li>■ do not exceed 3 [insert dosage unit(s)] in a 24-hour period</li> </ul>
Adults over 65 years	<ul style="list-style-type: none"> <li>■ do not take more than 1 [insert dosage unit] every 12 hours unless directed by a doctor</li> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li>■ ask a doctor</li> </ul>

#### **Other information**

- **each [insert dosage unit] contains:** sodium 20 mg
- optional - tamper evident statement
- store at 20-25° C (68-77° F). Avoid high humidity and excessive heat above 40° C (104° F)
- optional - see [end or side] panel for lot number and expiration date

**Inactive Ingredients** [list ingredients in alphabetical order]

**Questions or comments?** call toll free **1-800-XXX-XXXX**

NOTE: The **Drug Facts (continued)** title should appear wherever the labeling continues onto another panel of the package.